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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,183	03/02/2002	Ralph A. Reisfeld	TSRI 829.0	4743

7590 09/22/2005

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EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,183	REISFELD ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8, 10 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/24/05;4/28/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

After further consideration, new rejections were considered to be applicable to the claims; therefore, the finality of the previous office action is withdrawn. Because prosecution on the merits has been re-opened, applicants request for a pre-appeal brief is rendered moot.

Claim Objections

Claim 32 is objected to because of the following informalities: "comprising a vaccine of claim 1" should be "comprising the vaccine of claim 1". Appropriate correction is required.

Claim 34 is objected to because of the following informalities: "construct is polynucleotide"" should be "construct is the polynucleotide". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,2, 4-8, 10, and 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for reasons of record and for reasons outlined below.

Response to Arguments

Applicant's arguments filed 8/24/2005 have been fully considered but they are not persuasive. Applicants argue that newly cited references by Marshall et al and Schlom et al

demonstrate the ability of recombinant vaccines to induce immune responses. Otherwise, applicants present no new arguments from those submitted on 11/23/2004, which were responded to in full in the rejection of 2/24/2005.

First, both references are post-filing date and cannot be used to enable the instant invention because they could not have taught one of skill in the art how to make and use the claimed invention at the time of filing. Furthermore, Marshall et al is a description of a phase I clinical trial of a vaccine directed to an antigen unrelated to the instant claims (CEA) using an unrelated avipox vector. Phase I clinical trials, as detailed in Marshall et al, are designed to test toxicity, not efficacy. See page 727, first column documenting that due to the phase I nature of the trial, any results should be considered "trends" that "merit further study" and also see page 730, second column, first full paragraph which states any clinical results must be interpreted with caution (many of the patients received prior therapy) and that the study was designed to evaluate toxicity.

Schlom et al suffers from the same problems as Marshall et al, in that is directed to antigens unrelated to the instant claims (CEA or Muc-1) using unrelated avipox vectors.

It should be noted that this enablement rejection stems from the use of the word "vaccine" in the claims. Applicants appear to have implicit support (i.e. in Examples 1 and 2) for the claimed composition in the context of an attenuated, transformed *Salmonella typhimurium* cell if it were claimed as a "therapeutic composition" or "DNA composition" rather than a "vaccine".

New Grounds of Rejection

It is noted that this Office Action contains rejections of the same claims under 35 USC 112, 1st (enablement) and 35 USC 102 (b). While these rejections may seem contradictory, they are not because each is based upon a different legal analysis, i.e. sufficiency of the disclosure of the instant application to support claims under 35 USC 112, 1st paragraph vs. sufficiency of a prior art disclosure to anticipate or render obvious an embodiment(s) of the claimed invention (See *in re Hafner,* 161 USPQ 783 (CCPA 1969)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Quinn et al (PNAS, 1993, cited by applicants on the IDS of 4/28/2003). Upon further consideration, it is deemed that the intended use of the claimed composition as a DNA vaccine is not limiting. Therefore, the claims read on a DNA construct operably encoding a VEGF receptor in a pharmaceutically acceptable carrier. The encoded VEGF may be a VEGF-2 or Flk-1 (SEQ ID NO: 6), and the DNA construct may be a naked DNA, may be in a plasmid vector, or may be the polynucleotide of SEQ ID NO: 5. Lacking a definition in the specification, a pharmaceutically acceptable carrier is taken to be any buffer commonly used in handling DNA.

Quinn et al teach the "corrected" DNA and amino acid sequence of Flk-1/VEGF-2 (see page 7535, second column, second paragraph of the Discussion) originally published by Mathews et al (PNAS, 1991, cited by applicants on the IDS of 4/28/2003), and defined by applicants in the instant specification to be SEQ ID NO: 5 (DNA) and SEQ ID NO: 6 (amino acid) (see paragraph [0062] of the published patent application or page 13, lines 25-31 of the specification). Flk-1 was placed in the expression vectors pSV7d or pBluescript (i.e. plasmids, and considered to be naked DNA) and used to transfect COS cells or in *in vitro* transcription assays, both of which require buffers (see Materials and Methods, pages 7533-7534).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1633

CELIAN QIAN
PATENT EXAMINER